APPENDIX I

Table Shells for Unique Summary Tables

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Table 14.1.1 Summary of Subject Disposition, by Treatment and Overall
(All Subjects)

	Active snus (N=XXX)	Placebo snus (N=XXX)	Total (N=XXX)
Randomised at Baseline	XXX (100.0%)	XXX (100.0%)	XXX (100.0%)
Withdrawn before Week 24	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Withdrawn before Week 48	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Attended Week 24 Visit	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Completed the Study	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Study Populations:			
Intent-To-Treat Population	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Modified Intent-To-Treat Population	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Safety Population	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)

Note: The denominator of percentage is the number of randomised subjects in each group, and their total.

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The data presented in this Table are contained in Listings 16.2.1, 16.2.3 and 16.4.1

Programming note: Total N is the total number of subjects randomised. If necessary, document in footnote if any treatment errors occur (this effects Safety Population which uses treatment group as received).

Table 14.1.2 Summary of Final Status and Reason for Withdrawal, by Treatment and Overall
(All Subjects)

	Active snus (N=XXX)	Placebo snus (N=XXX)	Total (N=XXX)
Completed Study	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Withdrawn from Study	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Primary Reason for Withdrawal [1]:			
Failure to Achieve Smoking Reduction at Week 24	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Protocol Violation	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Lost to follow-up	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Withdrawal of Consent	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Adverse Event (Adverse Reaction)	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Death	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Other	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)

Note: Percentages are calculated using the population number in each treatment group (N) as the denominator.
[1] Percentages are calculated using the population number within each treatment group that withdrew from the study after randomisation.

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The data presented in this Table are contained in Listings 16.2.1 and 16.4.1

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Table 14.1.3.1 Summary of Subject Demographics, by Treatment and Overall
(ITT Population)

		Active snus (N=XXX)	Placebo snus (N=XXX)	Total (N=XXX)
Gender	Male	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
	Female	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Age (years)	N	XXX	XXX	XXX
	Mean	XX.X	XX.X	XX.X
	SD	XX.X	XX.X	XX.X
	Median	XX.X	XX.X	XX.X
	Minimum	XX	XX	XX
	Maximum	XX	XX	XX
Weight at Baseline (kg)	N	XXX	XXX	XXX
	Mean	XXX.XX	XXX.XX	XXX.XX
	SD	XXX.XX	XXX.XX	XXX.XX
	Median	XXX.XX	XXX.XX	XXX.XX
	Minimum	XXX.X	XXX.X	XXX.X
	Maximum	XXX.X	XXX.X	XXX.X
Height (cm)	N	XXX	XXX	XXX
	Mean	XXX.X	XXX.X	XXX.X
	SD	XXX.X	XXX.X	XXX.X
	Median	XXX.X	XXX.X	XXX.X
	Minimum	XXX	XXX	XXX
	Maximum	XXX	XXX	XXX
Body Mass Index (kg/m^2)	N	XXX	XXX	XXX
	Mean	XX.XX	XX.XX	XX.XX
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.XX	XX.XX	XX.XX
	Minimum	XX.X	XX.X	XX.X

Maximum	XX.X	XX.X	XX.X

Note: Percentages are calculated using the population number in each treatment group (N) as the denominator. Percentages are calculated using the number of subjects with available data. Percentages may not sum to 100% due to missing assessments.

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The data presented in this Table are contained in Listings 16.2.4.1 and 16.4.5

This layout also applies to:
Table 14.1.3.2 Summary of Subject Demographics, by Treatment and Overall (MITT Population)
Table 14.1.3.3 Summary of Subject Demographics, by Treatment and Overall (Safety Population)

Programming Note: Table 14.1.3.3 is only necessary in the event that any subjects receive treatment other than their randomised treatment, or if any randomised subjects do not receive treatment.

Table 14.1.4 Summary of Smoking History by Treatment and Overall
(ITT Population)

		Active snus (N=XXX)	Placebo snus (N=XXX)	Total (N=XXX)
Age of Initiation of Daily Smoking (Years)	N	XXX	XXX	XXX
	Mean	XX.X	XX.X	XX.X
	SD	XX.X	XX.X	XX.X
	Median	XX.X	XX.X	XX.X
	Minimum	XX	XX	XX
	Maximum	XX	XX	XX
Average Number of Cigarettes Smoked per day during the past year	N	XXX	XXX	XXX
	Mean	XX.X	XX.X	XX.X
	SD	XX.X	XX.X	XX.X
	Median	XX.X	XX.X	XX.X
	Minimum	XX	XX	XX
	Maximum	XX	XX	XX
Total Number of Quit Attempts	N	XXX	XXX	XXX
	Mean	XX.X	XX.X	XX.X
	SD	XX.X	XX.X	XX.X
	Median	XX.X	XX.X	XX.X
	Minimum	XX	XX	XX
	Maximum	XX	XX	XX
Intention to participate: Want to:	Quit Smoking	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
	Reduce Smoking	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Previously used NRT?	Yes	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
	No	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Previously used other Pharmaceutical Aids?	Yes	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
	No	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)

Previously used other Smoking Cessation Aids?	Yes	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
	No	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)

Note: Percentages are calculated using the population number in each treatment group (N) as the denominator. Percentages may not sum to 100% due to missing assessments.

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The data presented in this Table are contained in Listing 16.2.4.2

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Table 14.1.5 Summary of Compliance by Treatment, Visit and Overall
(Safety Population)

Visit			Active snus (N=XXX)	Placebo snus (N=XXX)	Total (N=XXX)
Week 1	Tried to use study products at least once a day	Yes	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
		No	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
	Used any source of nicotine other than cigarettes or snus	Yes	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
		No	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Week 2	Tried to use study products at least once a day	Yes	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
		No	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
	Used any source of nicotine other than cigarettes or snus	Yes	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
		No	XXX (XX.X%)	XXX (XX.X%)	XXX (XX.X%)
Week 6	Etc.				
Week 9	Etc.				
Week 12	Etc.				
Week 18	Etc.				
Week 24	Etc.				
Week 30	Etc.				
Week 36	Etc.				
Week 48	Etc.				

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The data presented in this Table are contained in Listing 16.2.5

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Table 14.1.6 Summary of Past Medical History by Treatment and Overall, System Organ Class and Preferred Term (ITT Population)

System Organ Class MedDRA Preferred Term	Active snus (N=XXX)			Placebo snus (N=XXX)			Total (N=XXX)		
	n	N	%	n	N	%	n	N	%
Any Medical Conditions	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
System Organ Class 1	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
Preferred Term 1	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
Preferred Term 2	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc
System Organ Class 2	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
Preferred Term 1	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
Preferred Term 2	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc
Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc

n=Number of Conditions Reported, N=Number of Patients, %=Percentage of Patients.

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Table are contained in Listing 16.4.4

Similar layout will also apply to the following tables:
Table 14.1.7 Summary of Concomitant Medical Conditions by Treatment and Overall, System Organ Class and Preferred Term (ITT Population)

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Table 14.1.8 Summary of Prior Medications by Treatment and Overall, ATC and Preferred Term
(ITT Population)

ATC Classification Preferred Term	Active snus (N=XXX)			Placebo snus (N=XXX)			Total (N=XXX)		
	n	N	%	n	N	%	n	N	%
Any Prior Medications		XX	(XX.X%)		XX	(XX.X%)		XX	(XX.X%)
ATC 1	XX	XX	(XX.X%)	XX	XX	(XX.X%)	XX	XX	(XX.X%)
Preferred Term 1	XX	XX	(XX.X%)	XX	XX	(XX.X%)	XX	XX	(XX.X%)
Preferred Term 2	XX	XX	(XX.X%)	XX	XX	(XX.X%)	XX	XX	(XX.X%)
Preferred Term 3	XX	XX	(XX.X%)	XX	XX	(XX.X%)	XX	XX	(XX.X%)
Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc
ATC 2	XX	XX	(XX.X%)	XX	XX	(XX.X%)	XX	XX	(XX.X%)
Preferred Term 1	XX	XX	(XX.X%)	XX	XX	(XX.X%)	XX	XX	(XX.X%)
Preferred Term 2	XX	XX	(XX.X%)	XX	XX	(XX.X%)	XX	XX	(XX.X%)
Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc

n=Number of Medications Reported, N=Number of Patients, %=Percentage of Patients.

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The data presented in this Table are contained in Listing 16.4.6

Similar layout will also apply to the following tables:
Table 14.1.9 Summary of Concomitant Medications at Randomisation by Treatment and Overall, ATC and Preferred Term (ITT Population) – *(contained in Listing 16.4.7.1)*
Table 14.3.3 Summary of Changes in Concomitant Medication by Treatment and Overall, ATC and Preferred Term (ITT Population) – *(contained in Listing 16.4.7.2)*

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Table 14.2.1.1 Summary and Analysis of Proportion of Subjects who Achieved Smoking Reduction at Week 24
(ITT Population)

		Active snus (N = XXX)	Placebo snus (N = XXX)
Smoking Reduction Achieved	Yes	XXX (XX.X%)	XXX (XX.X%)
	No	XXX (XX.X%)	XXX (XX.X%)
	Total	XXX(100.0%)	XXX (100.0%)
Treatment Comparison [1] (Active snus vs Placebo snus)	Odds Ratio Estimate (95% CI)	XX.X (XX.XX , XX.XX)	
	p-value	0.XXX	
		Parameter estimate (S.E)	p-value
	Centre	XXX.XX (XXX.XX)	0.XXX
	Age	XXX.XX (XXX.XX)	0.XXX
	Gender	XXX.XX (XXX.XX)	0.XXX
	Treatment x Centre Interaction	XXX.XX (XXX.XX)	0.XXX

Note: Subjects who discontinued the study prior to Week 24 for any reason are considered as failures (Response = No).

Model used is: Smoking Reduction Achieved (Yes/No) = Treatment + Centre + Age + Gender + Treatment x Centre Interaction.
[1] An odds ratio <1 = the odds of smoking reduction on Active snus is less than the odds of smoking reduction on Placebo snus
An odds ratio >1 = the odds of smoking reduction on Active snus is greater than the odds of smoking reduction on Placebo snus

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The data presented in this Table are contained in Listing 16.2.6.1

Programming Note: If the interaction term is not significant at 10% level (i.e. p ≥ 0.1), exclude this term from the final model, the table and the footnote. If the interaction term is significant (i.e. p < 0.1), include in the final model as shown in the table shell and repeat the top section of the table (Smoking Reduction Achieved: Yes; No; Total) for each centre individually.

Similar layout will also apply to the following tables:

Note: Each of the following tables respectively will only be produced if there are subjects in that population who meet the criteria described in the table title.

Table 14.2.1.2 Summary and Analysis of Proportion of Subjects who Achieved Smoking Reduction at Week 12 (ITT Population)
Change 'Week 24' to 'Week 12' in the footnote.

Table 14.2.1.3 Summary and Analysis of Proportion of Subjects who Achieved Smoking Cessation for One Week prior to Week 12 (ITT Population)
Change 'Reduction' to 'Cessation' and 'Week 24' to 'Week 12' in the table and footnotes.

Table 14.2.1.4 Summary and Analysis of Proportion of Subjects who Achieved Smoking Cessation for Four Weeks prior to Week 12 (ITT Population)
Change 'Reduction' to 'Cessation' and 'Week 24' to 'Week 12' in the table and footnotes.

Table 14.2.1.5 Summary and Analysis of Proportion of Subjects who Achieved Smoking Cessation for One Week prior to Week 24 (ITT Population)
Change 'Reduction' to 'Cessation' in the table and footnotes.

Table 14.2.1.6 Summary and Analysis of Proportion of Subjects who Achieved Smoking Cessation for Four Weeks prior to Week 24 (ITT Population)
Change 'Reduction' to 'Cessation' in the table and footnotes.

Table 14.2.1.7 Summary and Analysis of Proportion of Subjects who Achieved Smoking Cessation for One Week prior to Week 36 (ITT Population)
Change 'Reduction' to 'Cessation' and 'Week 24' to 'Week 36' in the table and footnotes.

Table 14.2.1.8 Summary and Analysis of Proportion of Subjects who Achieved Smoking Cessation for Four Weeks prior to Week 36 (ITT Population)
Change 'Reduction' to 'Cessation' and 'Week 24' to 'Week 36' in the table and footnotes.

Table 14.2.1.9 Summary and Analysis of Proportion of Subjects who Achieved Smoking Cessation for 12 Weeks prior to Week 36 (ITT Population)
Change 'Reduction' to 'Cessation' and 'Week 24' to 'Week 36' in the table and footnotes.

Table 14.2.1.10 Summary and Analysis of Proportion of Subjects who Achieved Smoking Cessation for 24 Weeks prior to Week 36 (ITT Population)
Change 'Reduction' to 'Cessation' and 'Week 24' to 'Week 36' in the table and footnotes.

Table 14.2.1.11 Summary and Analysis of Proportion of Subjects who Achieved Smoking Cessation for One Week prior to Week 48 (ITT Population)
Change 'Reduction' to 'Cessation' and 'Week 24' to 'Week 48' in the table and footnotes.

Table 14.2.1.12 Summary and Analysis of Proportion of Subjects who Achieved Smoking Cessation for Four Weeks prior to Week 48 (ITT Population)
Change 'Reduction' to 'Cessation' and 'Week 24' to 'Week 48' in the table and footnotes.

Table 14.2.1.13 Summary and Analysis of Proportion of Subjects who Achieved Smoking Cessation for 12 Weeks prior to Week 48 (ITT Population)
Change 'Reduction' to 'Cessation' and 'Week 24' to 'Week 48' in the table and footnotes.

Table 14.2.1.14 Summary and Analysis of Proportion of Subjects who Achieved Smoking Cessation for 24 Weeks prior to Week 48 (ITT Population)
Change 'Reduction' to 'Cessation' and 'Week 24' to 'Week 48' in the table and footnotes.

Table 14.2.1.15 Summary of Extent of Smoking Reduction Compared to Baseline by Treatment and Visit
(ITT Population)

Visit	Extent of Smoking Reduction	Active snus (N=XXX)	Placebo snus (N = XXX)
Week 12	0 - <25%	XXX (XX.X%)	XXX (XX.X%)
	25 - <50%	XXX (XX.X%)	XXX (XX.X%)
	50 - <75%	XXX (XX.X%)	XXX (XX.X%)
	75 - <100%	XXX (XX.X%)	XXX (XX.X%)
	100%	XXX (XX.X%)	XXX (XX.X%)
	Missing	XXX (XX.X%)	XXX (XX.X%)
Week 24	0 - <25%	XXX (XX.X%)	XXX (XX.X%)
	25 - <50%	XXX (XX.X%)	XXX (XX.X%)
	50 - <75%	XXX (XX.X%)	XXX (XX.X%)
	75 - <100%	XXX (XX.X%)	XXX (XX.X%)
	100%	XXX (XX.X%)	XXX (XX.X%)
	Missing	XXX (XX.X%)	XXX (XX.X%)
Week 36	0 - <25%	XXX (XX.X%)	XXX (XX.X%)
	Etc		
Week 48	0 - <25%	XXX (XX.X%)	XXX (XX.X%)
	Etc		

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The data presented in this Table are contained in Listing 16.2.6.5

Programming Note: Only include the Missing categories if there are subjects for whom it is not possible to derive the Extent of Smoking Reduction category due to lack of data.

Table 14.2.1.16 Summary of Smoking Status at Week 48 for Subjects who Discontinued at Week 24
(ITT Population minus MITT Population)

		Active snus (N=XXX)	Placebo snus (N = XXX)
Have you stopped smoking completely since Week 24? [1]	Yes	XXX (XX.X%)	XXX (XX.X%)
	No	XXX (XX.X%)	XXX (XX.X%)
Did you stop smoking completely between Week 36 and Week 48? [2]	Yes	XXX (XX.X%)	XXX (XX.X%)
	No	XXX (XX.X%)	XXX (XX.X%)
Did you stop smoking completely between Week 44 and Week 48? [3]	Yes	XXX (XX.X%)	XXX (XX.X%)
	No	XXX (XX.X%)	XXX (XX.X%)
CO in Exhaled Air (ppm)	N	XXX	XXX
	Mean	X.X	X.X
	SD	X.X	X.X
	Median	X	X
	Minimum	X	X
	Maximum	X	X

[1] If call took place at theoretical Week 48 +/- 1 week, question asked was "Have you stopped smoking completely since the Week 24 Visit?"; If call took place after theoretical Week 48 +/- 1 week, question asked was "Did you stop smoking completely for at least 16 weeks after the Week 24 visit?"
[2] If call took place at theoretical Week 48 +/- 1 week, question asked was "Did you stop smoking completely during the past 12 weeks?"; call took place after theoretical Week 48 +/- 1 week, question asked was "Did you stop smoking completely during Week 36 to Week 48?"
[3] If call took place at theoretical Week 48 +/- 1 week, question asked was "Did you stop smoking completely during the past 4 weeks?"; call took place after theoretical Week 48 +/- 1 week, question asked was "Did you stop smoking completely during Week 44 to Week 48?"

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Table are contained in Listing 16.4.11

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Table 14.2.2.1 Statistical Analysis of Carbon Monoxide (CO) in Exhaled Air (ppm)
(ITT Population)

			Active snus (N=XXX)	Placebo snus (N = XXX)
Baseline	CO in Exhaled Air	LSMean	XX.XX	XX.XX
		SE	XX.XX	XX.XX
	Treatment Difference	LSMEan	XX.X	
	(Active snus vs Placebo snus)	95% CI	(XX.XX , XX.XX)	
		p-value	0.XXX	
Week 2	CO in Exhaled Air	LSMean	XX.XX	XX.XX
		SE	XX.XX	XX.XX
	Treatment Difference	LSMEan	XX.X	
	(Active snus vs Placebo snus)	95% CI	(XX.XX , XX.XX)	
		p-value	0.XXX	
Week 6	Etc.			
Overall	CO in Exhaled Air	LSMean	XX.XX	XX.XX
		SE	XX.XX	XX.XX
	Treatment Difference	LSMEan	XX.X	
	(Active snus vs Placebo snus)	95% CI	(XX.XX , XX.XX)	
		p-value	0.XXX	
	Week Number	p-value	0.XXX	
	Centre	p-value	0.XXX	
	Treatment x Week Number Interaction	p-value	0.XXX	
	Treatment x Centre Interaction	p-value	0.XXX	
	Baseline CO in Exhaled Air	p-value	0.XXX	

LSMean = Least Squares Mean. SE = Standard Error. CI = Confidence Interval.

Mixed Effects Repeated Measures model used is: CO in Exhaled Air = Treatment + Week Number + Centre + Treatment x Week Number Interaction + Treatment x Centre Interaction + Baseline CO in Exhaled Air

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM
The data presented in this Table are contained in Listing 16.2.6.2

Programming Notes:

- *Continue the table display for Baseline and Weeks 2, 6, 12, 18, 24, 30, 36, 42 and 48*
- *If the treatment x week number interaction term is not significant at the 10% level (i.e. p ≥ 0.1), exclude this term from the final model, the table and the footnote. If the interaction term is significant (i.e. p < 0.1), include in the final model as shown in the table shell.*
- *If the treatment x centre interaction term is not significant at 10% level (i.e. p ≥ 0.1), exclude this term from the final model, the table and the footnote. If the interaction term is significant (i.e. p < 0.1), include in the final model as shown in the table shell and repeat the table for each centre individually.*

Similar layout will also apply to the following tables:
Table 14.2.2.2 Statistical Analysis of Carbon Monoxide (CO) in Exhaled Air (ppm) (MITT Population)

(Baseline and Weeks 12, 24, 36 and 48):
Table 14.2.3.1.1 Statistical Analysis of FEV1 (Litres) (ITT Population) – *(contained in Listing 16.2.6.3)*
Table 14.2.3.1.2 Statistical Analysis of FEV1 (Litres) (MITT Population) – *(contained in Listing 16.2.6.3)*
Change 'CO in Exhaled Air' to 'FEV1' in table and footnotes.
Table 14.2.3.2.1 Statistical Analysis of FVC (Litres) (ITT Population) – *(contained in Listing 16.2.6.3)*
Table 14.2.3.2.2 Statistical Analysis of FVC (Litres) (MITT Population) – *(contained in Listing 16.2.6.3)*
Change 'CO in Exhaled Air' to 'FVC' in table and footnotes.
Table 14.2.3.3.1 Statistical Analysis of FEV% (ITT Population) – *(contained in Listing 16.2.6.3)*
Table 14.2.3.3.2 Statistical Analysis of FEV% (MITT Population) – *(contained in Listing 16.2.6.3)*
Change 'CO in Exhaled Air' to 'FEV%' in table and footnotes.

(Baseline and all weekly results from Week 1 to Week 48):
Table 14.2.5.1 Statistical Analysis of Average Number of Cigarettes Smoked Per Day (ITT Population) – *(contained in Listing 16.2.6.5)*
Table 14.2.5.2 Statistical Analysis of Average Number of Cigarettes Smoked Per Day (MITT Population) – *(contained in Listing 16.2.6.5)*
Change 'CO in Exhaled Air' to 'Average # Cigarettes Per Day' in table and footnotes.

(Baseline and Weeks 6, 12, 24, 36 and 48):

Table 14.2.6.1 Statistical Analysis of Systolic Blood Pressure (mmHg) (ITT Population) – *(contained in Listing 16.4.5)*
Change 'CO in Exhaled Air' to 'Systolic Blood Pressure' in table and footnotes.
Table 14.2.6.2 Statistical Analysis of Diastolic Blood Pressure (mmHg) (ITT Population) – *(contained in Listing 16.4.5)*
Change 'CO in Exhaled Air' to 'Diastolic Blood Pressure' in table and footnotes.
Table 14.2.6.3 Statistical Analysis of Weight (kg) (ITT Population) – *(contained in Listing 16.4.5)*
Change 'CO in Exhaled Air' to 'Weight' in table and footnotes.
Table 14.2.6.4 Statistical Analysis of Body Mass Index (kg/m^2) (ITT Population) – *(contained in Listing 16.4.5)*
Change 'CO in Exhaled Air' to 'BMI' in table and footnotes.

(Baseline and Weeks 12, 24, 36 and 48):
Table 14.2.7.1 Statistical Analysis of Total S-WBC (10^9/L) (ITT Population) – *(contained in Listing 16.2.8)*
Change 'CO in Exhaled Air' to 'Total S-WBC' in table and footnotes.
Table 14.2.7.2 Statistical Analysis of S-CRP (mg/L) (ITT Population) – *(contained in Listing 16.2.8)*
Change 'CO in Exhaled Air' to 'S-CRP' in table and footnotes.
Table 14.2.7.3 Statistical Analysis of Total S-Cholesterol (mmol/L) (ITT Population) – *(contained in Listing 16.2.8)*
Change 'CO in Exhaled Air' to 'Total S-Cholesterol' in table and footnotes.
Table 14.2.7.4 Statistical Analysis of S-HDL (mmol/L) (ITT Population) – *(contained in Listing 16.2.8)*
Change 'CO in Exhaled Air' to 'S-HDL' in table and footnotes.
Table 14.2.7.5 Statistical Analysis of S-LDL (mmol/L) (ITT Population) – *(contained in Listing 16.2.8)*
Change 'CO in Exhaled Air' to 'S-LDL' in table and footnotes.
Table 14.2.7.6 Statistical Analysis of S-Fibrinogen (g/L) (ITT Population) – *(contained in Listing 16.2.8)*
Change 'CO in Exhaled Air' to 'S-Fibrinogen' in table and footnotes.
Table 14.2.7.6 Statistical Analysis of S-Fibrinogen (g/L) (ITT Population) – *(contained in Listing 16.2.8)*
Change 'CO in Exhaled Air' to 'S-Fibrinogen' in table and footnotes.
Table 14.2.7.7 Statistical Analysis of S-Cotinine (ng/mL) (ITT Population) – *(contained in Listing 16.2.8)*
Change 'CO in Exhaled Air' to 'S-Cotinine' in table and footnotes.

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Table 14.2.2.3.1 Summary of Carbon Monoxide (CO) in Exhaled Air (ppm) by Treatment and Visit
(ITT Population)

Visit		Active snus (N=XXX)		Placebo snus (N = XXX)	
		Actual	CFB	Actual	CFB
Baseline	N	XXX		XXX	
	Mean	X.X		X.X	
	SD	X.X		X.X	
	Median	X		X	
	Minimum	X		X	
	Maximum	X		X	
Week 2	N	XXX	XXX	XXX	XXX
	Mean	X.X	X.X	X.X	X.X
	SD	X.X	X.X	X.X	X.X
	Median	X	X	X	X
	Minimum	X	X	X	X
	Maximum	X	X	X	X
Week 6	N	XXX	XXX	XXX	XXX
Etc	Etc	Etc	Etc	Etc	Etc

CFB = Change from Baseline

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Table are contained in Listing 16.2.6.2

Programming Note: CO in Exhaled Air is recorded at Baseline and Weeks 2, 6, 12, 18, 24, 30, 36, 42 and 48.

Similar layout will also apply to the following tables:

Table 14.2.2.3.2 Summary of Carbon Monoxide (CO) in Exhaled Air (ppm) by Treatment and Visit, by Extent of Smoking Reduction Category (ITT Population)

Repeat the table layout for each of the following categories: 0 – <25%, 25 – <50%, 50 – <75$, 75 – <100%, 100%

(Baseline and Weeks 12, 24, 36 and 48):
Table 14.2.3.1.3.1 Summary of FEV1 (Litres) by Treatment and Visit (ITT Population) – *(contained in Listing 16.2.6.3)*
Table 14.2.3.1.3.2 Summary of FEV1 (Litres) by Treatment and Visit, by Extent of Smoking Reduction Category (ITT Population)
Repeat the table layout for each of the following categories: 0 - <25%, 25 - <50%, 50 - <75$, 75 - <100%, 100%

Table 14.2.3.2.3.1 Summary of FVC (Litres) by Treatment and Visit (ITT Population) – *(contained in Listing 16.2.6.3)*
Table 14.2.3.2.3.2 Summary of FVC (Litres) by Treatment and Visit, by Extent of Smoking Reduction Category (ITT Population)
Repeat the table layout for each of the following categories: 0 - <25%, 25 - <50%, 50 - <75$, 75 - <100%, 100%

Table 14.2.3.3.3.1 Summary of FEV% by Treatment and Visit (ITT Population) – *(contained in Listing 16.2.6.3)*
Table 14.2.3.3.3.2 Summary of FEV% by Treatment and Visit, by Extent of Smoking Reduction Category (ITT Population)
Repeat the table layout for each of the following categories: 0 - <25%, 25 - <50%, 50 - <75$, 75 - <100%, 100%

(Baseline and all weekly results from Week 1 to Week 48):
Table 14.2.5.3 Summary of Average Number of Cigarettes Smoked Per Day by Treatment and Week (ITT Population) – *(contained in Listing 16.2.6.5) – Change first column header to 'Week' and summarise Baseline and all weeks from Week 1 to Week 48.*
Add footnote: "Baseline results summarise average number of cigarettes per day during the previous year. Week 1 to Week 48 results summarise the average number of cigarettes per day during the previous week."

Table 14.2.4.1 Summary and Analysis of Fagerström Test at Baseline, Week 24 and Week 48
(ITT Population)

			Active snus (N=XXX)		Placebo snus (N=XXX)	
			Actual	CFB	Actual	CFB
Baseline	Total Score	N	XXX		XXX	
		Minimum	XX		XX	
		25% quartile	XX.X		XX.X	
		Median	XX.X		XX.X	
		75% quartile	XX.X		XX.X	
		Maximum	XX		XX	
	Wilcoxon Rank Sum Test (Active snus vs. Placebo snus)	p-value	0.XXX			
		Median difference	X.XX			
		95% CI	(X.XX, X.XX)			
Week 24	Total Score	N	XXX	XXX	XXX	XXX
		Minimum	XX	XX	XX	XX
		25% quartile	XX.X	XX.X	XX.X	XX.X
		Median	XX.X	XX.X	XX.X	XX.X
		75% quartile	XX.X	XX.X	XX.X	XX.X
		Maximum	XX	XX	XX	XX
	Wilcoxon Rank Sum Test (Active snus vs. Placebo snus)	p-value	0.XXX			
		Median difference	X.XX			
		95% CI	(X.XX, X.XX)			
Week 48	Etc.					

Note: Subjects who were not assessed at Week 24 or Week 48 due to either stopping smoking in the previous week or discontinuation from the study have been excluded from the summary and analysis at that visit.

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Table are contained in Listing 16.2.6.4

Similar layout will also apply to the following tables:
Table 14.2.4.2 Summary and Analysis of Fagerström Test at Baseline, Week 24 and Week 48 (MITT Population)

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Table 14.2.5.4 Summary of Snus Use Per Day by Treatment and Week
(ITT Population)

Week		Active snus (N=XXX)			Placebo snus (N = XXX)		
		Large (1g) Sachets Consumed	Small (0.5g) Sachets Consumed	Amount of Snus Consumed (g)	Large (1g) Sachets Consumed	Small (0.5g) Sachets Consumed	Amount of Snus Consumed (g)
Week 1	N	XXX	XXX	XXX	XXX	XXX	XXX
	Mean	X.X	X.X	XX.X	X.X	X.X	XX.X
	SD	X.X	X.X	X.X	X.X	X.X	X.X
	Median	X	X	XX	X	X	XX
	Minimum	X	X	XX	X	X	XX
	Maximum	X	X	XX	X	X	XX
Week 2	N	XXX	XXX	XXX	XXX	XXX	XXX
	Mean	X.X	X.X	XX.X	X.X	X.X	XX.X
	SD	X.X	X.X	X.X	X.X	X.X	X.X
	Median	X	X	XX	X	X	XX
	Minimum	X	X	XX	X	X	XX
	Maximum	X	X	XX	X	X	XX
Week 3	N	XXX	XXX		XXX	XXX	
Etc	Etc	Etc	Etc		Etc	Etc	

Note: Results for Large (1g) and Small (0.5g) Sachets summarise the number of large and small snus sachets respectively consumed on average per day during the previous week. Amount of snus Consumed (g) is calculated for each subject as the number of large sachets consumed + 0.5 x the number of small sachets consumed per day during the previous week.

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Table are contained in Listing 16.2.6.5

Programming Note: Summarise all weeks from Week 1 to Week 48.

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Table 14.2.6.5.1 Summary of Vital Signs, by Treatment, Visit and Overall
(ITT Population)

Parameter	Visit		Active snus (N=XXX)		Placebo snus (N=XXX)		Total (N=XXX)	
			Actual	CFB	Actual	CFB	Actual	CFB
Systolic BP (mmHg)	Baseline	N	XXX		XXX		XXX	
		Mean	XX.XX		XX.XX		XX.XX	
		SD	XX.XX		XX.XX		XX.XX	
		Median	XX.XX		XX.XX		XX.XX	
		Minimum	XX.X		XX.X		XX.X	
		Maximum	XX.X		XX.X		XX.X	
	Week 6	N	XXX	XXX	XXX	XXX	XXX	XXX
		Etc	Etc	Etc	Etc	Etc	Etc	Etc
	Week 12	N	XXX	XXX	XXX	XXX	XXX	XXX
		Etc	Etc	Etc	Etc	Etc	Etc	Etc
	Etc							
Diastolic BP (mmHg)	Baseline	N	XXX	XXX	XXX	XXX	XXX	XXX
		Etc	Etc	Etc	Etc	Etc	Etc	Etc
	Etc							
Weight (kg)	Baseline	N	XXX	XXX	XXX	XXX	XXX	XXX
		Etc	Etc	Etc	Etc	Etc	Etc	Etc
	Etc							
BMI (kg/m^2)	Baseline	N	XXX	XXX	XXX	XXX	XXX	XXX
		Etc	Etc	Etc	Etc	Etc	Etc	Etc
	Etc							

BP = Blood Pressure, BMI = Body Mass Index, CFB = Change from Baseline

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM
The data presented in this Table are contained in Listing 16.4.5

Similar layout will also apply to the following tables:
Table 14.2.6.5.2 Summary of Vital Signs, by Treatment, Visit and Overall, by Extent of Smoking Reduction Category (ITT Population)

Repeat the table layout for each of the following categories: 0 - <25%, 25 - <50%, 50 - <75$, 75 - <100%, 100%

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Table 14.2.7.8.1 Summary of Laboratory Parameters by Treatment, Visit and Overall
(ITT Population)

Parameter	Visit		Active snus (N=XXX)		Placebo snus (N=XXX)		Total (N=XXX)	
			Actual	CFB	Actual	CFB	Actual	CFB
Hematology:								
Total S-WBC (10^9/L)	Baseline	N	XXX		XXX		XXX	
		Mean	XX.XX		XX.XX		XX.XX	
		SD	XX.XX		XX.XX		XX.XX	
		Median	XX.XX		XX.XX		XX.XX	
		Minimum	XX.X		XX.X		XX.X	
		Maximum	XX.X		XX.X		XX.X	
	Week 12	N	XXX	XXX	XXX	XXX	XXX	XXX
		Etc	Etc	Etc	Etc	Etc	Etc	Etc
	Week 24	N	XXX	XXX	XXX	XXX	XXX	XXX
		Etc	Etc	Etc	Etc	Etc	Etc	Etc
	Etc							
Chemistry:								
S-CRP (mg/L)	Baseline	N	XXX	XXX	XXX	XXX	XXX	XXX
		Etc	Etc	Etc	Etc	Etc	Etc	Etc
	Etc							
Total S-Cholesterol (mmol/L)	Baseline	N	XXX	XXX	XXX	XXX	XXX	XXX
		Etc	Etc	Etc	Etc	Etc	Etc	Etc
	Etc							
S-HDL (mmol/L)	Baseline	N	XXX	XXX	XXX	XXX	XXX	XXX
		Etc	Etc	Etc	Etc	Etc	Etc	Etc
	Etc							

S-LDL (mmol/L)	Baseline	N	XXX	XXX	XXX	XXX	XXX	XXX
		Etc	Etc	Etc	Etc	Etc	Etc	Etc
	Etc							
S-Fibrinogen (g/L)	Baseline	N	XXX	XXX	XXX	XXX	XXX	XXX
		Etc	Etc	Etc	Etc	Etc	Etc	Etc
	Etc							
S-Cotinine (ng/mL)	Baseline	N	XXX	XXX	XXX	XXX	XXX	XXX
		Etc	Etc	Etc	Etc	Etc	Etc	Etc
	Etc							

CFB = Change from Baseline

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Table are contained in Listing *16.2.8*

Similar layout will also apply to the following tables:
Table 14.2.7.8.2 Summary of Laboratory Parameters by Treatment, Visit and Overall, by Extent of Smoking Reduction Category (ITT Population)

Repeat the table layout for each of the following categories: 0 - <25%, 25 - <50%, 50 - <75$, 75 - <100%, 100%

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Table 14.3.1.1 Summary of Adverse Events by Treatment and Overall
(Safety Population)

	Active snus (N=XXX)			Placebo snus (N=XXX)			Total (N=XXX)		
	n	N	%	n	N	%	n	N	%
Any Adverse Events	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
Serious Adverse Events	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
Adverse Events Related to Study Treatment	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
Adverse Events Leading to Discontinuation of Study Treatment	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)

n=Number of Events Reported, N=Number of Subjects, %=Percentage of Subjects.

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Table are contained in Listing 16.2.7

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Table 14.3.1.2.1 Summary of Adverse Events by System Organ Class, Preferred Term, Treatment and Overall (Safety Population)

System Organ Class MedDRA Preferred Term	Active snus (N=XXX)			Placebo snus N=XXX)			Total (N=XXX)		
	n	N	%	n	N	%	n	N	%
Any Adverse Events	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
System Organ Class 1	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
Preferred Term 1	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
Preferred Term 2	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
Etc									
System Organ Class 2	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
Preferred Term 1	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
Preferred Term 2	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
Etc									
Etc									

n=Number of Events Reported, N=Number of Subjects, %=Percentage of Subjects.

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Table are contained in Listing 16.2.7

Similar layout will also apply to the following tables:
Table 14.3.1.2.2 Summary of Serious Adverse Events by System Organ Class, Preferred Term, Treatment and Overall (Safety Population) – *(contained in Table 14.3.2.2)*
Table 14.3.1.2.3 Summary of Treatment-Related Adverse Events by System Organ Class, Preferred Term, Treatment and Overall (Safety Population) – *(contained in Listing 16.2.7)*
Table 14.3.1.2.4 Summary of Adverse Events Leading to Discontinuation of Study Treatment by System Organ Class, Preferred Term, Treatment and Overall (Safety Population) – *(contained in Table 14.3.2.3)*

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Table 14.3.1.3.1 Summary of Adverse Events Severity by Treatment, System Organ Class and Preferred Term
(Safety Population)

Treatment: Active snus (N=XXX)

System Organ Class MedDRA Preferred Term	Mild			Moderate			Severe			Not Applicable		
	n	N	%	n	N	%	n	N	%	n	N	%
Any Adverse Events	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
System Organ Class 1	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
Preferred Term 1	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
Preferred Term 2	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc
System Organ Class 2	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
Preferred Term 1	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
Preferred Term 2	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)	XXX	XXX	(XX.X%)
Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc
Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc

n=Number of Events Reported, N=Number of Subjects, %=Percentage of Subjects.

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM
The data presented in this Table are contained in Listing 16.2.7

Repeat for Placebo snus and Total.

Similar layout will also apply to the following tables:
Table 14.3.1.3.2 Summary of Serious Adverse Events Severity by Treatment, System Organ Class and Preferred Term (Safety Population) – *(contained in Table 14.3.2.2)*
Table 14.3.1.3.3 Summary of Treatment-Related Adverse Events Severity by Treatment, System Organ Class and Preferred Term (Safety Population) – *(contained in Listing 16.2.7)*

Table 14.3.1.3.4 Summary of Adverse Events Leading to Discontinuation of Study Treatment Severity by Treatment, System Organ Class and Preferred Term (Safety Population) – *(contained in Table 14.3.2.3)*

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Table 14.3.2.1 Listing of Adverse Events Leading to Death
(Safety Population)

Treatment: Active snus, Site Number: XX

Subject Number	System Organ Class Preferred Term Adverse Event	Start Date	Stop Date / Ongoing	Severity [1]	Study Drug Action Taken [2]	Concomitant Therapy due to AE	Relationship to Study Drug [3]	Outcome [4]	Serious
XXXX	XXXXXXXXXXXXXXX XXXXXXXXXXXXXX XXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY / Ongoing	1/2/3/4	1/2/3	Yes/No	1/2/3/4/5	1/2/3/4/5	Yes/No
	XXXXXXXXXXXXXXX XXXXXXXXXXXXXX XXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY / Ongoing	1/2/3/4	1/2/3	Yes/No	1/2/3/4/5	1/2/3/4/5	Yes/No
XXXX									
Etc	Etc								

[1] Severity: 1=Mild, 2=Moderate, 3=Severe, 4=Not Applicable;
[2] Study Drug Action Taken: 1=None, 2=Dose Interrupted, 3=Discontinued;
[3] Relationship to Study Drug: 1=Unrelated, 2=Unlikely, 3=Possibly, 4=Probably, 5=Definitely;
[4] Outcome: 1= Resolved with no Sequelae, 2=Resolved with Sequelae, 3=Death, 4=Unknown, 5=Lost to Follow Up;

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF pages 42 and 42.x

Repeat for Treatment: Placebo snus and for all sites

Programming Note: In Listing 14.3.2.1, the Outcome column should be 3 (Death) for all records, and the Serious column should be Yes for all records.

Similar layout will also apply to the following tables:
Table 14.3.2.2 Listing of Serious Adverse Events (Safety Population)

Table 14.3.2.3 Listing of Adverse Events Leading to Discontinuation of Study Treatment (Safety Population)

APPENDIX II

Layout for Data Listings

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.2.1 Discontinued Subjects

Treatment	Site Number	Subject Number	Date Withdrawn	Primary Reason for Discontinuation
Active snus	XX	XXXX	DDMMMYYYY	Failure to achieve smoking reduction at Week 24 or Protocol Violation or Lost to Follow Up or Withdrawal of Consent or Adverse Event (Adverse Reaction) or Death or Other: *Specify*
	Etc	Etc		Etc
Placebo snus	Etc	Etc		Etc

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF page 39

Listing 16.2.2 Informed Consent

Treatment	Site Number	Subject Number	Date Informed Consent Signed
Active snus	XX	XXXX	DDMMMYYYY
		Etc	Etc
Placebo snus	XX	XXXX	DDMMMYYYY
		Etc	Etc

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF page 2

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.2.3 Subjects Included in Analysis Populations

Treatment	Site Number	Subject Number	Population		
			ITT	MITT	Safety
Active snus	XX	XXXX	Yes / No	Yes / No	Yes / No
		Etc	Etc	Etc	Etc
	Etc	Etc	Etc	Etc	Etc
Placebo snus	Etc	Etc	Etc	Etc	Etc

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.2.4.1 Demographic Data

Treatment	Site Number	Subject Number	Randomisation Date	Date of Birth	Age (years)	Gender
Active snus	XX	XXXX	DDMMMYYYY	DDMMMYYYY	XX	Male / Female
		Etc		Etc	Etc	Etc
	Etc	Etc		Etc	Etc	Etc
Placebo snus	Etc	Etc		Etc	Etc	Etc

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF page 2

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.2.4.2 Smoking History

Treatment	Site Number	Subject Number	Age of Initiation of Daily Smoking	Average Number of Cigarettes per Day during Past Year	Total Quit Attempts	Intention to Participate	Previous NRT?	Previous Pharm. Aids?	Previous Cessation Aids?
Active snus	XX	XXXX	XX	XX	XX	Want to quit smoking or Want to reduce smoking	Yes/No	Yes/No	Yes/No
	Etc	Etc	Etc	Etc	Etc	Etc			
	Etc	Etc	Etc	Etc	Etc	Etc			
Placebo snus	Etc	Etc	Etc	Etc	Etc	Etc			

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF page 2

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.2.5 Compliance

Treatment	Site Number	Subject Number	Visit	Question	Response
Active snus	XX	XXXX	Week 1	Tried to use study products at least once a day	Yes/No
				Used any source of nicotine other than cigarettes or snus	Yes/No
			Week 2	Tried to use study products at least once a day	Yes/No
				Used any source of nicotine other than cigarettes or snus	Yes/No
			Week 6	Tried to use study products at least once a day	Yes/No
				Used any source of nicotine other than cigarettes or snus	Yes/No
			Etc.	Etc.	
Placebo snus	Etc.	Etc.	Etc.	Etc.	
			Etc.	Etc.	

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF pages 7, 8, 11, 12, 15, 18, 24, 26, 30 and 38

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.2.6 Subjects Who Received Study Treatment Different to Randomised Treatment

Site Number	Subject Number	Randomised Treatment	Visit	Log Label Number	Actual Treatment
XX	XXXX	Active snus	Baseline	XXXX	Active snus
			Week 2	XXXX	Placebo snus
				XXXX	Placebo snus
			Week 6	XXXX	Active snus
				XXXX	Active snus
			Week 12	XXXX	Active snus
				XXXX	Active snus
			Week 18	XXXX	Active snus
				XXXX	Active snus
			Week 24	XXXX	Active snus
				XXXX	Active snus
			Etc.		
		Placebo snus	Baseline	XXXX	Active snus
			Etc.		
		Etc.			
Etc.	Etc.	Etc.			

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

Programming Note: Subjects may receive multiple logs at each visit. This listing should only contain the data for subjects who received at least one log that did not contain their randomised treatment. It is possible that logs dispensed did not correspond to individual subject preference of sachet size and/or snus flavour – such subjects will not appear in this listing as long as the study treatment received matches the randomised treatment for all records.

List all visits at which treatment logs were dispensed to each subject: Baseline, Weeks 2, 6, 12, 18, 24, 30, 36 and 48

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.2.6.1 Efficacy Assessments

Treatment	Site Number	Subject Number	Visit	Endpoint	Response
Active snus	XX	XXXX	Week 12	Achieved Smoking Reduction	Yes/No
				Achieved Smoking Cessation: 1 Week Period	Yes/No
				Achieved Smoking Cessation: 4 Week Period	Yes/No
			Week 24	Achieved Smoking Reduction	Yes/No
				Achieved Smoking Cessation: 1 Week Period	Yes/No
				Achieved Smoking Cessation: 4 Week Period	Yes/No
			Week 36	Achieved Smoking Cessation: 1 Week Period	Yes/No
				Achieved Smoking Cessation: 4 Week Period	Yes/No
				Achieved Smoking Cessation: 12 Week Period	Yes/No
				Achieved Smoking Cessation: 24 Week Period	Yes/No
			Week 48	Achieved Smoking Cessation: 1 Week Period	Yes/No
				Achieved Smoking Cessation: 4 Week Period	Yes/No
				Achieved Smoking Cessation: 12 Week Period	Yes/No
				Achieved Smoking Cessation: 24 Week Period	Yes/No
	XX	XXXX	Week 12	Etc	Etc
Placebo snus	XX	XXXX	Week 12	Etc	Etc

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF pages 15, 22, 30 and 36

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.2.6.2 Carbon Monoxide (CO) in Exhaled Air

Treatment	Site Number	Subject Number	Visit	CO in Exhaled Air (ppm)	
				Actual	CFB
Active snus	XX	XXXX	Baseline	XXX	
			Week 2	XXX	XXX
			Week 6	XXX	XXX
			Week 12	XXX	XXX
			Week 18	XXX	XXX
			Week 24	XXX	XXX
			Week 30	XXX	XXX
			Week 36	XXX	XXX
			Week 42	XXX	XXX
			Week 48	XXX	XXX
	XX	XXXX	Baseline	XXX	
			Etc	Etc	Etc
Placebo snus	XX	XXXX	Baseline	XXX	
			Etc	Etc	Etc

CFB: Change from Baseline

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF pages 3, 8, 10, 13, 17, 19, 25, 27, 32 and 33

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.2.6.3 Lung Function Tests

Treatment	Site Number	Subject Number	Visit	Test (Units)	Actual Result	Change from Baseline
Active snus	XX	XXXX	Baseline	FEV1 (Litres) FVC (Litres) FEV% (%)	X.XX X.XX XXX	
			Week 12	FEV1 (Litres) FVC (Litres) FEV% (%)	X.XX X.XX XXX	X.XX X.XX XXX
			Week 24	Etc	Etc	Etc
			Week 36	Etc	Etc	Etc
			Week 48	Etc	Etc	Etc
	XX	XXXX	Baseline	Etc	Etc	
			Etc	Etc	Etc	Etc
Placebo snus	XX	XXXX	Baseline	Etc	Etc	
			Etc	Etc	Etc	Etc

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF pages 3, 13, 19, 27 and 33

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.2.6.4 Fagerström Test

Treatment	Site Number	Subject Number	Visit	Question		Response
Active snus	XX	XXXX	Baseline	How soon after you wake up do you smoke your first cigarette?	0 or 1 or 2 or 3	After 60 minutes or 31-60 minutes or 6-30 minutes or Within 5 minutes
				Do you find it difficult to refrain from smoking in places where it is forbidden?	0/1	No/Yes
				Which cigarette would you hate most to give up?	1 or 0	The first in the morning or Any other
				How many cigarettes per day do you smoke?	0 or 1 or 2 or 3	10 or less or 11-20 or 21-30 or 31 or more
				Do you smoke more frequently during the first hours after awakening than during the rest of the day?	0/1	No/Yes
				Do you smoke even if you are so ill that you are in bed most of the day?	0/1	No/Yes
				Total	XX	
			Week 24	Have you stopped smoking during the past week?		No/Yes
				Etc	Etc	Etc.

			Week 48	Have you stopped smoking during the past week?			No/Yes
				Etc		Etc	Etc
Placebo snus	Etc	Etc	Etc	Etc		Etc	Etc

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF pages 5, 23 and 37

Programming Note: At Weeks 24 and 48, if the subject stopped smoking during the previous week then the Fagerström test is not performed.

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.2.6.5 Self-Reported Smoking Status

Treatment Group	Site Number	Subject Number	Week	Average Number Cigarettes per Day [1]	Tobacco Products other than Cigarettes	If Yes, Specify	Snus Sachets Consumed Per Day		Total Amount of Snus Consumed Per Day (g)
							Large (1g)	Small (0.5g)	
Active snus	XX	XXXX	Baseline	XXX	Yes/No	XXXXXXXXXX XXXXXXXXXX			
			Week 1	XXX			XXX	XXX	XXX
			Week 2	XXX			XXX	XXX	XXX
			Etc						
			Week 48	XXX			XXX	XXX	XXX
	XX	XXXX	Baseline	Etc					
Placebo snus	Etc	Etc	Etc	Etc					

[1] Average number of cigarettes per day during the past year at Baseline and during the past week post Baseline

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF pages 6, 10, 12, 14, 17, 21, 25, 29, 32 and 35

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.2.7 Adverse Events

Treatment: Active snus, Site Number: XX

Subject Number	System Organ Class Preferred Term Adverse Event	Start Date	Stop Date / Ongoing	Severity [1]	Study Drug Action Taken [2]	Concomitant Therapy due to AE	Relationship to Study Drug [3]	Outcome [4]	Serious
XXXX	XXXXXXXXXXXXXXX XXXXXXXXXXXXXX XXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY / Ongoing	1/2/3/4	1/2/3	Yes/No	1/2/3/4/5	1/2/3/4/5	Yes/No
	XXXXXXXXXXXXXXX XXXXXXXXXXXXXX XXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY / Ongoing	1/2/3/4	1/2/3	Yes/No	1/2/3/4/5	1/2/3/4/5	Yes/No
XXXX									
Etc	Etc								

[1] Severity: 1=Mild, 2=Moderate, 3=Severe, 4=Not Applicable;
[2] Study Drug Action Taken: 1=None, 2=Dose Interrupted, 3=Discontinued;
[3] Relationship to Study Drug: 1=Unrelated, 2=Unlikely, 3=Possibly, 4=Probably, 5=Definitely;
[4] Outcome: 1= Resolved with no Sequelae, 2=Resolved with Sequelae, 3=Death, 4=Unknown, 5=Lost to Follow Up;

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF pages 42 and 42.x

Repeat for Treatment: Placebo snus and for all sites

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.2.8 Laboratory Parameters

Treatment: Active snus

Site Number	Subject Number	Visit	Category	Blood Test	Result in Original Units	Original Units	Result in Standard Units	Standard Units	Flag	Normal Range in Standard Units
XX	XXXX	Baseline	Hematology	Total S-WBC	XXX	XXXXX	XXX	10^9/L	L/ N/ H	4-10
			Chemistry	S-CRP	XXX	XXXXX	XXX	mg/L	L/ N/ H	0-5
				Total S-Cholesterol	XXX	XXXXX	XXX	mmol/L	L/ N/ H	0-5
				S-HDL	XXX	XXXXX	XXX	mmol/L	L/ N/ H	>=1.55
				S-LDL	XXX	XXXXX	XXX	mmol/L	L/ N/ H	0-2.5
				S-Fibrinogen	XXX	XXXXX	XXX	g/L	L/ N/ H	2-3.3
				S-Cotinine	XXX	XXXXX	XXX	ng/mL	L/ N/ H	>25
		Week 12	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc
		Week 24	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc
		Week 36	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc
		Week 48	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc
XX	XXXX	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc
XX	XXXX	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc

L: Low, N: Normal, H: High

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF pages 4, 14, 20, 28 and 34

Repeat for Treatment: Placebo snus

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.4.1 Final Status

Treatment: Active snus, Site Number: XX

Subject Number	Study Completed	Date Completed or Withdrawn	Primary Reason for Discontinuation	Treatment Unblinded?	If Yes, Date of Unblinding	Reason for Unblinding	Investigator Name	Investigator Signature Date
XXXX	Yes / No	DDMMMYYYY	Failure to achieve smoking reduction at Week 24 or Protocol Violation or Lost to Follow Up or Withdrawal of Consent or Adverse Event (Adverse Reaction) or Death or Other: *Specify*	Yes/No	DDMMMYYYY	XXXXXXXXXXX	XXXXXXXX	DDMMMYYYY
Etc	Etc							

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF page 39

Repeat for Treatment: Placebo snus and for all Sites

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.4.2 Inclusion Criteria

Inclusion Criteria Number	Inclusion Criteria Detail
1	Is the subject able to understand the requirements of the study and provide written informed consent to participate?
2	Is the subject male or female between the ages of 20 and 65 years, inclusive?
3	The subjects smokes 10 or more cigarettes per day (average during the past month)
4	The subject smokes daily and has done so for more than 1 year
5	The subject is motivated to substantially reduce or quit smoking
6	The subject is in good general health
7	The subject accepts not to take NRT or any other non-protocol treatment to facilitate smoking cessation, and accepts not to use any other form of tobacco products other than cigarettes during the study period

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF page 1

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.4.2 Inclusion Criteria

Treatment	Site Number	Subject Number	Inclusion Criteria						
			1	2	3	4	5	6	7
Active snus	XX	XXXX	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		XXXX	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		XXXX	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		XXXX	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc
	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc
Placebo snus	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF page 1

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.4.3 Exclusion Criteria

Exclusion Criteria Number	Exclusion Criteria Detail
1	Does the subject have uncontrolled hypertension (systolic >140 mmHg, diastolic >90 mmHg)?
2	Does the subject have a history of coronary heart disease or other significant heart condition?
3	Does the subject have a history of another significant medical condition which may interfere with study procedures?
4	Is the subject a pregnant or nursing mother?
5	Does the subject currently abuse alcohol or drugs?
6	Does the subject currently have active oral disease that may interfere with the use of snus?
7	Does the subject have significant psychiatric or psychosocial problems that may interfere with study procedures?
8	Has the subject used any type of pharmaceutical or other products for smoking reduction or cessation within the past 3 months?

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF page 1

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.4.3 Exclusion Criteria

Treatment	Site Number	Subject Number	Exclusion Criteria							
			1	2	3	4	5	6	7	8
Active snus	XX	XXXX	Yes / No	Yes / No	Yes/ No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		XXXX	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		XXXX	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		XXXX	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc
	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc
Placebo snus	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF page 1

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.4.4 Medical History and Current Medical Conditions

Treatment	Site Number	Subject Number	Previous / Current Condition	Response	System Organ Class MedDRA Preferred Term Medical Condition
Active snus	XX	XXXX	Previous	Yes	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
			Current	Yes	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
		XXXX	Previous	No	
		XXXX	Current	No	
Placebo snus	XX	XXXX	Previous	Etc	Etc
			Current	Etc	Etc

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF page 3

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.4.5 Vital Signs

Treatment	Site Number	Subject Number	Visit	Blood Pressure (mmHg)						Weight (kg)		Height (cm)	Body Mass Index (kg/m^2)
				Systolic			Diastolic						
				Actual	CFB		Actual	CFB		Actual	CFB		
Active snus	XX	XXXX	Baseline	XXX			XXX			XXX		XXX	XX.X
			Week 6	XXX	XXX	*	XXX	XXX	*	XXX	XXX		
			Week 12	XXX	XXX		XXX	XXX		XXX	XXX		
			Week 24	XXX	XXX		XXX	XXX		XXX	XXX		
			Week 36	XXX	XXX	*	XXX	XXX	*	XXX	XXX		
			Week 48	XXX	XXX		XXX	XXX		XXX	XXX		
		XXXX	Etc	Etc	Etc		Etc	Etc		Etc	Etc	Etc	Etc
Placebo snus	XX	XXXX	Etc	Etc	Etc		Etc	Etc		Etc	Etc	Etc	Etc

* Clinically Significant CFB: Change from Baseline
Note: Weight is recorded without shoes.

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF pages 3, 10, 13, 19, 27 and 33

Programming Note: The data contains 'NCS' when blood pressure results are not clinically significant. The '' will need to be shown in this listing when 'NCS' is not present in the data. Note that NCS information is not recorded at the Baseline visit, so no Baseline results should be marked with '*' in this listing.*

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.4.6 Prior Medications

Treatment: Active snus

Site Number	Subject Number	Medication ATC Term (ATC Code) Preferred Term	Indication	Dose	Units	Frequency [1]	Route [2]	Start Date	Stop Date	Ongoing?
XX	XXXX	XXXXXXXXXXXXXXXXXXXXX XXXXXXXXX (XXXXXXX) XXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXX	XXX	XXXXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	Yes / No
		Etc	Etc		Etc			Etc	Etc	Etc
	Etc	Etc	Etc		Etc			Etc	Etc	Etc
Etc	Etc	Etc	Etc		Etc			Etc	Etc	Etc

[1] Frequency: OD=Once a Day, BID=Twice a Day, TID=Three Times a Day, QID=Four Times a Day, QOD=Every Other Day, QW=Once a Week, PRN=As Needed
[2] Route: IM=Intramuscular, PO=Oral, IV=Intravenous, SC=Subcutaneous, IN=Intranasal, MDI=Meter Dose Inhaler, DPI=Dry Powder Inhaler

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF pages 41 and 41.x

Repeat for Treatment: Placebo snus

Programming Note: The last column should only be presented in Listings 16.4.7.1 and 16.4.7.2

This layout will also apply to the following listings:
Listing 16.4.7.1 Concomitant Medications
Listing 16.4.7.2 Changes to Concomitant Medications

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.4.8 Preferences to Flavour and Size of Study Product at Week 1

Treatment	Site Number	Subject Number	Category	Response
Active snus	XX	XXXX	Preferred flavour of snus sachets	Eucalyptus / Liquorice
			Preferred size of snus sachets	0.5g (Small) / 1g (Large)
		XXXX	Preferred flavour of snus sachets	Eucalyptus / Liquorice
		XXXX	Preferred size of snus sachets	0.5g (Small) / 1g (Large)
Placebo snus	XX	XXXX	Preferred flavour of snus sachets	Eucalyptus / Liquorice
			Preferred size of snus sachets	0.5g (Small) / 1g (Large)
		Etc	Etc	Etc

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF page 7

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.4.9 Comments

Treatment	Site Number	Subject Number	Date of Comment	CRF Page Number	Comment
Active snus	XX	XXXX	DDMMMYYYY	XX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
			DDMMMYYYY	XX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
		XXXX	DDMMMYYYY	XX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
			DDMMMYYYY	XX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Placebo snus	XX	XXXX	DDMMMYYYY	XX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
			DDMMMYYYY	XX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
		Etc			Etc

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF pages 43 and 43.x

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.4.10 Unscheduled Visits

Treatment	Site Number	Subject Number	Date of Visit	Visit Week	Reason for Visit
Active snus	XX	XXXX	DDMMMYYYY	XX.X	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
			DDMMMYYYY	XX.X	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
		XXXX	DDMMMYYYY	XX.X	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
			DDMMMYYYY	XX.X	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Placebo snus	XX	XXXX	DDMMMYYYY	XX.X	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
			DDMMMYYYY	XX.X	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
		Etc			Etc

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF pages 40.x

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.4.11 Smoking Status at Week 48 for Subjects Discontinued Due to Not Achieving Smoking Reduction at Week 24

Question Number	Question if Call is at Theoretical Week 48 +/- 1 Week	Question if Call is After Theoretical Week 48 +/- 1 Week
1	Have you stopped smoking completely since the Week 24 visit?	Did you stop smoking completely for at least 16 weeks after the Week 24 visit?
2	Did you stop smoking completely during the past 12 weeks?	Did you stop smoking completely during Week 36 to Week 48?
3	Have you stopped smoking completely during the past 4 weeks?	Did you stop smoking completely during Week 44 to Week 48?

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF Appendix I

Swedish Match AB – Protocol No. SM 07-01 Page X of Y

Listing 16.4.11 Smoking Status at Week 48 for Subjects Discontinued Due to Not Achieving Smoking Reduction at Week 24

Treatment	Site Number	Subject Number	Date of Telephone Interview	Date of Last Visit	Response to Question 1	Response to Question 2	Response to Question 3	Date of Clinical Visit	CO in Exhaled Air
Active snus	XX	XXXX	DDMMMYYYY	DDMMMYYYY	Yes / No	Yes / No	Yes / No	DDMMMYYYY	XXX
			DDMMMYYYY	DDMMMYYYY	Yes / No	Yes / No	Yes / No	DDMMMYYYY	XXX
		XXXX	DDMMMYYYY	DDMMMYYYY	Yes / No	Yes / No	Yes / No	DDMMMYYYY	XXX
			DDMMMYYYY	DDMMMYYYY	Yes / No	Yes / No	Yes / No	DDMMMYYYY	XXX
Placebo snus	XX	XXXX	DDMMMYYYY	DDMMMYYYY	Yes / No	Yes / No	Yes / No	DDMMMYYYY	XXX
			DDMMMYYYY	DDMMMYYYY	Yes / No	Yes / No	Yes / No	DDMMMYYYY	XXX
		Etc	Etc	Etc	Etc	Etc	Etc	Etc	Etc

Program path: X:\xxx\xxxx\xxxxxxx.sas Executed: DDMMMYYYY, HH:MM

The data presented in this Listing are contained in CRF Appendix I